REMARKS

The Office Action dated May 31, 2007 ("Office Action") has been carefully considered. Paragraphs [00121], [00133], [00142], [00150] and [00161] of the specification have been amended to correct typographical errors.

Claims 1-22 are pending in the present application. Claims 1, 6, 7, 14 and 21 have been amended. Claim 1 has been amended to recite, *inter alia*, a liquid form controlled release drug composition comprising a pharmaceutically acceptable polyelectrolyte. Support for such amendment can be found at para. [0078], page 17. Claim 6 has been amended to more particularly point out and claim an embodiment of the present invention. Support for such amendment can be found at para. [0064], page 13. Claim 7 has been amended to correct dependency. Claim 14 has been amended to recite, *inter alia*, the composition of claim 1, as suggested by the Examiner. Claim 21 has been amended to more particularly point out and claim an embodiment of the present invention. Support for such amendment can be found at para. [0035], page 8 and para. [0093], page 20. No new matter has been added.

Claims 18-20 have been withdrawn from consideration. Applicants reserve the right to pursue subject matter recited in the withdrawn claims in one or more related applications. Reconsideration of the present application in view of the above amendments and the following remarks is respectfully requested.

I. CLAIM REJECTION UNDER 35 U.S.C. § 112 SHOULD BE WITHDRAWN

A. Claims 1-17 And 21 Are Rejected Under 35 U.S.C. § 112, First Paragraph

Claims 1-17 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner asserts that "the use of any polyelectrolyte without identifying the ions associated with the polyelectrolyte ...would not lead the artisan away from using polyelectrolytes having associated Hg or Ag ions." (Office Action at page 3). Applicants respectfully disagree. Applicants, however, amend claim 1 to recite a liquid form controlled release drug composition comprising, *inter alia*, a dispersion medium comprising a pharmaceutically acceptable polyelectrolyte. Thus, as amended, claim 1 would not lead one of ordinary skill in the art to use polyelectrolytes that are not acceptable for pharmaceutical compositions *e.g.* polyelectrolytes associated with Hg or Ag ions. Pharmaceutically acceptable polyelectrolytes are well known in the art and described by the examples in the instant specification. Claims 2-17 and 21 depend from

claim 1 and include all the recitations of claim 1. Thus, Applicants believe that this rejection has been overcome.

The Examiner has also rejected claim 21 under 35 U.S.C. § 112, first paragraph. The Examiner asserts that the specification fails to describe the "conditions" and "symptoms" treatable by the compositions of claim 1. Claim 21 has been amended to recite a method for treating a patient suffering from a condition or symptom, comprising administering a liquid form controlled release drug composition of claim 1 to a patient in need thereof, wherein the drug comprises a cardiovascular drug, respiratory drug, sympathomimetic drug, cholinomemetic drug, adrenergic drug, antimuscarinic drug, antispasmodic drug, skeletal muscle relaxant, diuretic drug, anti-migraine drug, anesthetic, sedative, hypnotic, antiepileptic, psychopharmacologic agent, analgesic, including opioid and non-opioid analgesic, antipyretic, CNS stimulant, antineoplastic, immunosuppressive drug, antimicrobial drug, antihistamine, anti-inflammatory, antibiotic, decongestant, cough suppressant, expectorant or a combination thereof.

Thus, one of ordinary skill in the art would understand that the conditions or symptoms recited in claim 21 are those that can be treated by the administration of a respiratory drug, sympathomimetic drug, cholinomemetic drug, adrenergic drug, antimuscarinic drug, antispasmodic drug, skeletal muscle relaxant, diuretic drug, anti-migraine drug, anesthetic, sedative, hypnotic, antiepileptic, psychopharmacologic agent, analgesic, including opioid and non-opioid analgesic, antipyretic, CNS stimulant, antineoplastic, immunosuppressive drug, antimicrobial drug, antihistamine, anti-inflammatory, antibiotic, decongestant, cough suppressant or expectorant. Thus, Applicants believe that this rejection has been overcome.

B. Claim 7 Is Rejected Under 35 U.S.C. § 112, Second Paragraph

Claim 7 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Claim 7 has been amended to depend from claim 5. Therefore, Applicants believe that this rejection has been overcome.

II. CLAIM OBJECTION UNDER 37 C.F.R. 1.75(c) SHOULD BE WITHDRAWN

Claim 7 is objected to under 37 C.F.R. 1.75(c), as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim. As discussed above, claim 7 has been amended to depend from claim 5. Therefore, Applicants believe that this objection has been overcome.

III. THE CLAIM REJECTIONS UNDER 35 U.S.C. § 102(b) SHOULD BE WITHDRAWN

All of the pending claims require *inter alia*, a liquid form controlled release drug composition comprising a dispersion medium comprising a pharmaceutically acceptable polyelectrolyte having the same charge as the electrolytic drug. For the reasons provided below, Applicants respectfully submit that none of the references cited by the Examiner disclose a dispersion medium comprising a pharmaceutically acceptable polyelectrolyte having the same charge as the electrolytic drug.

A. Cuna *et al.* ("Cuna") Does Not Anticipate Claims 1-3, 5-6, 8, 13-14 and 16 Under 35 U.S.C. § 102(b)

Claims 1-3, 5-6, 8, 13-14 and 16 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Cuna *et al.* "Controlled-release liquid suspensions based on ion-exchange particles entrapped within acrylic microcapsules," International Journal of Pharmaceutics 199 (2000), pp 151-158 ("Cuna"). This rejection is respectfully traversed.

Claim 1 recites a liquid form controlled release drug composition that includes, *inter alia*, an electrolytic drug associated with an ion exchange resin and a dispersion medium comprising a pharmaceutically acceptable polyelectrolyte having the same charge as the electrolytic drug.

Cuna discloses a controlled release liquid formulation of Eudragit®-coated microcapsules that contain terbutaline-loaded resins (Abstract). The formulation disclosed in Cuna has a dispersed phase having these Eudragit®-coated micocapsules (page 154, sec. 2.7). The dispersion medium is an aqueous solution of 0.75% w/w of hydroxymethcellulose (page 154, sec. 2.7). Hydroxymethylcellulose is a neutral polymer and, therefore, is not a pharmaceutically acceptable polyelectrolyte having a charge, let alone, a polyelectrolyte having the same charge as the cationic drug terbutaline. Thus, Cuna fails to teach or suggest a liquid form controlled release drug composition that includes *inter alia*, an electrolytic drug associated with an ion exchange resin and a dispersion medium comprising a pharmaceutically acceptable polyelectrolyte having the same charge as the electrolytic drug.

Claims 2-3, 5-6, 8, 13-14 and 16 depend from claim 1 and therefore include all the recitations of claim 1. Thus, Applicants believe that claims 1-3, 5-6, 8, 13-14 and 16 are patentable over Cuna and that the Examiner's rejection of claims 1-3, 5-6, 8, 13-14 and 16 should be withdrawn.

B. U.S. Patent No. 4,859,461 to Chow *et al.* or U.S. Patent No. 4,762,709 to Sheumaker or U.S. Patent No. 5,186,930 to Kogan *et al.* or U.S. Patent No. 4,996,047 to Kelleher *et al.* Do Not Anticipate Claims 1-6 and 13-17 Under 35 U.S.C. § 102(b)

Claims 1-6 and 13-17 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 4,859,461 to Chow *et al.* ("Chow") or U.S. Patent No. 4,762,709 to Sheumaker ("Sheumaker") or U.S. Patent No. 5,186,930 to Kogan *et al.* ("Kogan") or U.S. Patent No. 4,996,047 to Kelleher *et al.* ("Kelleher"). This rejection is respectfully traversed. Each of Chow, Sheumaker, Kogan or Kheller fail to teach or suggest a liquid form controlled release drug composition that includes, *inter alia,* an electrolytic drug associated with an ion exchange resin and a dispersion medium comprising a pharmaceutically acceptable polyelectrolyte having the same charge as the electrolytic drug.

Chow discloses sulfonic acid, cationic exchange resin particles containing the basic drug, phenylpropanolamine (col. 4, ll. 15-30). While Chow arguably suggests that such particles can be formulated in a liquid dosage form, such as a suspension of complex particles in a palatable vehicle or a controlled release dosage form (*see* col. 5, ll. 11-18); Chow does not disclose a liquid form controlled release drug composition that includes, *inter alia,* an electrolytic drug associated with an ion exchange resin and a dispersion medium comprising a pharmaceutically acceptable polyelectrolyte having the same charge as the electrolytic drug. Chow is silent with respect to any discussion of dispersion media for controlled release liquid formulations. In fact, the examples in Chow only disclose the preparation of resin complexes and not formed resin particles suspended in a liquid vehicle.

Sheumaker discloses a coated, drug-resin complex with an ionic compound suspended in a liquid carrier, which contains a second ionic compound present in an uncoated, insoluble drug-resin complex (col. 1, ll. 60-66). As such, both of the ionic resin complexes are in the dispersed phase of the liquid formulation. Sheumaker fails to disclose any dispersion medium that contains polyelectrolytes having the same charge as the drugs present in the resin complexes.

In Example 1 of Sheumaker, a sustained release formulation was prepared by suspending coated, drug-resin complexes containing the cationic drug pseudoephedrine and a second ionic compound, the cationic drug chlorpheniramine as an uncoated, insoluble drug-resin complex, in an aqueous solution containing xanthan gum (col. 3, ll. 8-55). Xanthan gum is a negatively charged polyelectrolyte. Thus, Sheumaker discloses a liquid form controlled release drug composition that includes, *inter alia,* a dispersion medium comprising a polyelectrolyte having the opposite charge of the cationic drugs pseudophedrine and

chlorpheniramine and not a liquid form controlled release drug composition that includes *inter alia,* a dispersion medium comprising a pharmaceutically acceptable polyelectrolyte having the same charge as the electrolytic drug. Accordingly, Sheumaker fails to teach or suggest a liquid form controlled release drug composition that includes *inter alia,* an electrolytic drug associated with an ion exchange resin and a dispersion medium comprising a pharmaceutically acceptable polyelectrolyte having the same charge as the electrolytic drug.

Kogan discloses a sustained release wax-and-polymer coated drug ion exchange resin complex suspended in a liquid carrier for oral administration (Abstract). Specifically, Example 1 of Kogan describes a sustained release wax-and-polymer coated drug ion exchange resin complex containing pseudoephedrine, a cationic drug, suspended in a solution containing xanthan gum, a negatively charged polyelectrolyte (col. 4, ll. 15-col. 6, ll. 15). Therefore, Kogan discloses a sustained release wax-and-polymer coated drug ion exchange resin complex suspended in a liquid carrier that has a polyelectrolyte with the opposite and not the same charge as the drug contained in the ion exchange resin. As such, Kogan fails to teach or suggest a liquid form controlled release drug composition that includes *inter alia,* an electrolytic drug associated with an ion exchange resin and a dispersion medium comprising a pharmaceutically acceptable polyelectrolyte having the same charge as the electrolytic drug.

Kelleher discloses coated drug-resin particles that can be suspended in an aqueous solution (Abstract, col. 5, ll. 66-67). Example XIV is the only liquid formulation disclosed specifically in Kelleher. The Example describes coated drug-resin particles containing pseudoephedrine suspended in an aqueous suspension that includes xanthan gum (col. 19, 35-54). As discussed above, pseudoephedrine is a cationic drug and xanthan gum is an anionic polyelectrolyte. Thus, Kelleher teaches coated drug-resin particles suspended in an aqueous suspension that includes a polyelectrolyte having the opposite charge and not the same charge as the drug contained in the resin. Kelleher fails to teach or suggest a liquid form controlled release drug composition that includes, *inter alia*, an electrolytic drug associated with an ion exchange resin and a dispersion medium comprising a polyelectrolyte having the same charge as the electrolytic drug.

Claims 2-6 and 13-17 depend from claim 1 and include all the recitations of claim 1. Thus, Applicants believe that claims 1-7 and 13-17 are patentable over Chow, Sheumaker, Kogan or Kelleher and that the Examiner's rejection should be withdrawn.

C. U.S. Patent No. 4,894,239 to Nonomura *et al.* Does Not Anticipate Claims 1-17 and 21 Under 35 U.S.C. § 102(b)

Claims 1-17 and 21 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 4,894,239 to Nonomura *et al.* ("Nonomura"). This rejection is respectfully traversed. Nonomura fails to teach or suggest a liquid form controlled release drug composition that includes, *inter alia,* an electrolytic drug associated with an ion exchange resin and a dispersion medium comprising a pharmaceutically acceptable polyelectrolyte having the same charge as the electrolytic drug.

Similar to Cuna, Nonomura only discloses a sustained-release microcapsule preparation that consists of an ion exchange resin containing a drug coated with a water permeable polymer that can be formulated into oral suspensions by dispersing the microcapsules in purified water (Abstract, 4, ll. 55-62). Nonomura is silent with respect to any dispersion medium containing polyelectrolytes. As such, Nonomura fails to disclose a liquid form controlled release drug composition that includes *inter alia,* an electrolytic drug associated with an ion exchange resin and a dispersion medium comprising a pharmaceutically acceptable polyelectrolyte having the same charge as the electrolytic drug.

Claims 2-17 and 21 depend from claim 1 and therefore include all the recitations of claim 1. Thus, Applicants believe that claims 1-17 and 21 are patentable over Nonomura and that the Examiner's rejection of claims 1-17 and 21 should be withdrawn.

IV. DOUBLE PATENTING REJECTION

Claims 1-17 and 21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-29 of co-pending application nos. 11/150,572 (US2006/0018972) and 11/198,937 (US2006/0134148) to Hollenbeck ("Hollenbeck") in view of WO 95/19184 to Cohen *et al.* ("Cohen").

Applicants disagree with the bases of the Examiner's rejection. However, Applicants respectfully request that the Examiner hold this provisional double-patenting rejection in abeyance. As the rejection involves pending applications rather than an issued patent, Applicants request that the Examiner withdraw the provisional double patenting rejection in the instant application and permit it to issue when no other rejections remain. *See* M.P.E.P. § 804(I)(B). The double patenting rejection can then be asserted in the pending applications, if applicable.

Thus, Applicants respectfully request that the Examiner hold this provisional double-patenting rejection in abeyance until either this application or any of the co-pending

Application Nos. 11/150,572 (US2006/0018972) and 11/198,937 (US2006/0134148) are allowed.

V. CONCLUSION

In light of the above amendments and remarks, it is believed that the claim rejections have been overcome and that the present application is in condition for allowance. Should the Examiner not agree with Applicants' position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

Respectfully submitted,

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